UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME CORP., Plaintiff, v. APOTEX INC. and APOTEX CORP., Defendants.	Case No. 15-2384 (PGS) (TJB) ***Document Filed Electronically*** **Return date: August 3, 2015**

APOTEX CORP.'S BRIEF IN SUPPORT OF ITS RULE 12(B)(6)
MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM

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Defendant Apotex Corp. ("Apotex") respectfully submits this brief in support of its Rule 12(b)(6) motion to dismiss the amended complaint for failure to state a claim.

INTRODUCTION

On April 2, 2015, Merck filed its original complaint. On May 12th, Apotex moved to dismiss for failure to state a claim, including because Merck's complaint: (1) "does not actually allege patent infringement"; and (2) was based on "speculative legal conclusions, not factual allegations." (D.I. 19-1 at 1). Two weeks later, on May 28th, Merck conceded Apotex's motion by filing an amended complaint. (*See* D.I. 24). Although this amended complaint recasts some of Merck's contingent and speculative allegations, the substance of Merck's allegations remains unchanged (or, more appropriately, the lack of substance remains the same).

Accordingly, Apotex moves to dismiss once again. Like the original complaint, the purportedly "amended" complaint fails to state a claim for two separate and independent reasons. *First*, the amended complaint does not actually allege infringement. The linchpin of the amended complaint is the following statement about a vague and theoretical "corresponding version" that Merck created to reword its allegations:

> And, because Defendants seek approval to manufacture, use, offer for sale, and/or sell ***a corresponding version*** in the United States, on information and belief, that product also ***would*** contain mometasone furoate monohydrate and ***would*** infringe at least claim 1 of the '353 patent.

(D.I. 24 ¶ 41).[1] This is a carefully re-worded contingency about a theoretical "version" of an unspecified product, not an allegation of infringement by an accused product. Because Merck still has not alleged actual patent infringement, its amended complaint should be dismissed.

Second, apparently attempting to obscure this foundational flaw, Merck alleges that, if it were possible that an unspecified Canadian product could infringe the 353 patent, then,

[1] Emphasis has been added, unless otherwise indicated.

"on information and belief," it is possible that a future "corresponding version" in the United States also "would" infringe the 353 patent. (D.I. 24 ¶ 41).[2] These are mere speculative legal conclusions, not factual allegations. Because these conclusory statements are not entitled to an assumption of truth, the complaint should be dismissed.

These glaring defects beg the question: Why did Merck file an amended complaint without a genuine allegation of patent infringement? As the original complaint conceded, because Merck lost the previous litigation, Merck is not entitled to advance notice of final FDA approval of the ANDA. (D.I. 1 ¶ 38). Merck will receive notice when actual U.S. product is launched. Thus, Merck's last gasp to delay launch is a contingent, speculative amended complaint to try to open the door to re-argue the many infringement theories that failed in the previous litigation.

Apotex respectfully submits that the Court should reject Merck's post-trial strategy and dismiss the amended complaint because it fails to state a cognizable claim. Merck had its chance to prove infringement, but failed.

FACTUAL BACKGROUND

As noted above, in response to Apotex's first motion to dismiss, Merck recast several of its contingent and speculative allegations. To assist the Court's analysis of these re-worded allegations, Apotex has prepared a "redline" reflecting Merck's changes to the original

[2] Importantly, Merck does not allege that Merck's own Canadian and United States mometasone nasal spray products are identical. In fact, it appears that there are differences, which may explain Merck's creation of the purposely vague and theoretical term "corresponding version." *See, e.g.*, *Product Monograph, Nasonex* (Merck Canada) at http://www.merck.ca/assets/en/pdf/products/NASONEX-PM_E.pdf (accessed 6/26/15); *Prescribing Information* (Merck U.S.) at http://www.merck.com/product/usa/pi_circulars/n/nasonex/nasonex_pi.pdf (accessed 6/26/15).

complaint. For ease of reference, the original complaint is attached as Exhibit 1; the amended complaint is attached as Exhibit 2; and the "redline" is attached as Exhibit 3.[3]

Essentially, as shown in the redlined excerpts below, Merck has simply recast what the original complaint called "modified Product" and "different" product as two equally vague and theoretical products: "New Product" and "corresponding version":

> 33. Thus, the generic mometasone furoate nasal spray offered by Apotex in Australia and Canada is the same product, and on information and belief, ~~Apotex~~Defendants will conform ~~its~~their U.S. mometasone furoate nasal spray product to ~~its~~Apotex's offerings elsewhere in the world in an effort to leverage lower production costs and maintain profits while offering ~~its~~their product at a substantially reduced price. Therefore, ~~Apotex~~if approved by the FDA, Defendants will ~~seek to~~ manufacture, use, offer for sale, and/or sell a product in the United States that is different than the product that ~~which~~ was the subject of the Previous Litigation (represented by HW9234~~.~~) (the "New Product").
>
> * * *
>
> 35. … In the event that Apotex had proposed modifications to its mometasone furoate nasal spray, Merck requested samples of the ~~modified~~ New Product. …
>
> * * *
>
> ~~36~~39. . . . Therefore, on information and belief, Merck must conclude from Defendants' failure to respond to Merck's ~~inquiry~~multiple inquiries that, if approved by the FDA, Defendants ~~already have sought or are planning on seeking to~~will manufacture, use, market, and/or sell ~~a~~their New Product in the United States ~~different than the product~~.
>
> 40. On information and belief, Defendants seek approval to manufacture, use, and/or sell a version of generic mometasone furoate nasal spray product in the United States that corresponds to the product offered elsewhere in the work including Canada.

[3] Exhibits are attached the Chamcharas Declaration, filed herewith.

> ~~37~~41. ~~On information and belief,~~ Merck has confirmed that the generic mometasone furoate nasal spray sold by Apotex in Canada contains mometasone furoate monohydrate. ~~On information and belief, to~~Therefore, the ~~extent that Apotex seeks to manufacture, use, offer for sale, and/or sell a generic version of~~ mometasone furoate nasal spray ~~product in the United States that uses a bottle different than the bottle used for samples provided to Merck in the Previous Litigation, such product would contain mometasone furoate in such a form as~~sold by Apotex in Canada would infringe at least claim 1 of the '353 patent~~.~~ if sold in the United States. And, because Defendants seek approval to manufacture, use, offer for sale, and/or sell a corresponding version in the United States, on information and belief, that product also would contain mometasone furoate monohydrate and would infringe at least claim 1 of the '353 patent.
>
> ~~38~~42. As a result of the Previous Litigation, Defendants would be able to launch ~~a generic version of Nasonex nasal spray~~ their New Product in the United States immediately upon regulatory approval, even ~~if~~though the ~~ultimately approved product was~~New Product is different than the product provided to Merck for testing in the Previous Litigation.

Merck's new labels, "New Product" and "corresponding version," add nothing of substance. The entire pleading still rests on the following contingent, hypothetical statements about a theoretical product in paragraph 41:

> 41. Merck has confirmed that the generic mometasone furoate nasal spray sold by Apotex in Canada contains mometasone furoate monohydrate. Therefore, the mometasone furoate nasal spray sold by Apotex in Canada would infringe at least claim 1 of the '353 patent if sold in the United States. And, because Defendants seek approval to manufacture, use, offer for sale, and/or sell a ***corresponding version*** in the United States, on information and belief, ***that product*** also ***would*** contain mometasone furoate monohydrate and ***would*** infringe at least claim 1 of the '353 patent.

(D.I. 24).

A close reading of this paragraph reveals that Merck does not actually allege patent infringement or identify an accused product. The first two statements are a legal conclusion that an unspecified Canadian product "would" infringe the 353 patent "if sold in the United States."[4] The third statement, made "on information and belief," suggests that any possible future U.S. "corresponding version . . . ***would*** contain mometasone furoate monohydrate and ***would*** infringe at least claim 1 of the '353 patent."

Read together, these allegations make a quantum leap from a legal conclusion about an alleged "monohydrate" in an unspecified Canadian product to speculation about how any "corresponding version" of an unspecified future U.S. product "would contain" the same alleged "monohydrate." Again, this is not a factual allegation of patent infringement by an accused product. It is a purely speculative and sweeping legal conclusion based on a series of unwarranted inferences.

Moreover, at least the following two paragraphs reveal the true purpose of Merck's complaint:

> 42. As a result of the Previous Litigation, Defendants would be able to launch their New Product in the United States immediately upon regulatory approval, even though the New Product is different than the product provided to Merck for testing in the Previous Litigation.
>
> * * *
>
> 44. Merck will not receive any ***warning or notification*** before the FDA approves Defendants' New Product.

[4] Significantly, as Apotex noted in its first motion to dismiss, although Merck obtained Australian product samples and concluded that they contain the "same formulation" and were "packaged in the same bottle" as Canadian product, Merck does not state that Australian product contains any "monohydrate" that would infringe the 353 patent. *See, e.g.*, D.I. 1 ¶¶ 31-32; D.I. 24 ¶¶ 31-32. Apotex asked Merck to explain this inconsistency, but Merck declined. *See* Exhibit 4.

(D.I. 24). In essence, through its conclusory and speculative complaint, Merck seeks to regain what it lost in the previous litigation: (1) advance notice of final FDA approval; (2) access to highly confidential business information; and (3) yet another chance to re-argue infringement.[5] Merck recently confirmed this true purpose by proposing "expediting discovery" and "accelerated/early discovery." *See* Exhibit 4.

LEGAL ARGUMENT

I. The dismissal standard.

The Court is well-versed in the Rule 12(b)(6) standard for failure to state a claim. *See, e.g.*, *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 538-39 (D.N.J. 2014) (Sheridan, J.) (discussing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009)); *Torrey v. New Jersey*, No. 13-1192, 2014 WL 941308, at *4 (D.N.J. Mar. 11, 2014) (Sheridan, J.); *In re Phillips/Magnavox Television Litig.*, No. 09-3072, 2010 WL 3522787, at *4 (D.N.J. Sep. 1, 2010) (Sheridan, J.).

Briefly, "when assessing the sufficiency of a complaint, a district court must distinguish factual contentions and '[t]hreadbare recitals of the elements of a cause of action, supported by ***mere conclusory statements***.'" *Lipitor*, 46 F. Supp. 3d at 538 (quoting *Iqbal*, 556 U.S. at 678). Any such mere conclusory statements are "not entitled to the assumption of truth." *Id*. at 539 (quoting *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011)). Similarly, the "tenet that a court must accept as true all of the allegations contained in a complaint is ***inapplicable to legal conclusions***." *Torrey*, 2014 WL 941308, at *4 (quoting *Iqbal*, 556 U.S. at 678). Moreover, a court should not "accept bald assertions, unsupported conclusions, unwarranted inferences, or

[5] If Merck had been able to prove any of its infringement theories in the previous litigation, Merck would have received advance notice of final FDA approval and likely launch—*i.e.*, upon expiration of the asserted patent. Having lost, Merck now is in the same position as any other alleged patent owner. Merck is not entitled to any type of advance notice, including through any proposed "expedited discovery" of highly confidential business information.

sweeping legal conclusions cast in the form of factual allegations." *Phillips*, 2010 WL 3522787, at *4. The "factual allegations must be enough to raise a right to relief above the speculative level." *Id* (quoting *Twombly*, 550 U.S. at 555).

II. The complaint should be dismissed.

The linchpin of Merck's complaint falls squarely within the inadequate pleadings described in *Iqbal* and *Twombly*. The starting point of Merck's alleged hypothetical infringement—the presence of a "monohydrate" in an unspecified Canadian product—is a mere conclusory statement. Although Merck had more than ample opportunity to evaluate Canadian product and amend its complaint with factual allegations, Merck's amended complaint simply replaces the "on information and belief" preface to one of its original allegations with the bare conclusion that "Merck has confirmed":[6]

> ~~37~~41. ~~On information and belief,~~Merck has confirmed that the generic mometasone furoate nasal spray sold by Apotex in Canada contains mometasone furoate monohydrate. ~~On information and belief, to~~Therefore, the ~~extent that Apotex seeks to manufacture, use, offer for sale, and/or sell a generic version of~~mometasone furoate nasal spray ~~product in the United States that uses a bottle different than the bottle used for samples provided to Merck in the Previous Litigation, such product would contain mometaone furoate in such a form as~~sold by Apotex in Canada would infringe at least claim 1 of the '353 patent~~.~~ if sold in the United States. And, because Defendants seek approval to manufacture, use, offer for sale, and/or sell a corresponding version in the United States, on information and belief, that product also would contain mometasone furoate monohydrate and would infringe at least claim 1 of the '353 patent.

(*See* D.I. 24). As Apotex noted in its first motion to dismiss, if Merck had credible test results showing that Canadian product contained "monohydrate," Merck would have pled these facts

[6] Merck alleges that Canadian product has been on sale since March 2013, so Merck has had over two years to evaluate Canadian product samples.

(and, presumably, Merck would have provided the results in response to Apotex's requests). (*See* D.I. 19-1 at 2 n.2). Instead, Merck's "amendment" states the same legal conclusion, adding only that "Merck has confirmed" its previous "belief," without any supporting factual allegation.

Even if Merck's alleged "confirmed" legal conclusion about unspecified Canadian product were found to be a factual allegation (it is not), Merck's attempt to link a theoretical "corresponding version" back to Canadian product fail. Like the original complaint, the amended complaint still hinges on contingencies that are further conditioned upon Merck's alleged "information and belief." These contingencies and caveats, both alone and taken together, render Merck's pleading deficient and require dismissal. *See, e.g.*, *In re Papst Licensing GMBH & Co. KG Litig.*, 585 F. Supp. 2d 32, 35 (D.D.C. 2008) ("The Complaint merely speculates that Sanyo might have infringed or be infringing and notifies Sanyo and the Court that Papst intends to investigate whether Papst has an infringement claim against Sanyo. Thus, the Complaint fails to state a claim . . . ."); *Ecodyne Corp. v. Croll-Reynolds Eng'g Co.*, 491 F. Supp. 194, 198 (D. Conn. 1979) ("The court is unwilling to adjudicate such speculative matters and finds that on the face of the complaint, there has been no sale of an allegedly infringing item."); *D.G. Rung Indus., Inc. v. Tinnerman*, 626 F. Supp. 1062, 1065 (W.D. Wash. 1986) ("There is no patent infringement under 35 U.S.C. § 271 when plaintiff alleges only intent and capability."); *Gen-Probe, Inc. v. Amoco Corp.*, 926 F. Supp. 948, 962 (S.D. Cal. 1996) ("Filing a patent infringement action pointing vaguely to 'products and/or kits' . . . does not reflect the reasonable inquiry required by the Rules."); *Level 1 Techs., Inc. v. C.R. Bard, Inc.*, 839 F. Supp. 90, 92 (D. Mass. 1994) ("To resolve actual disputes, ***not theoretical or speculative controversies***, is the fundamental function of the federal courts.").

Layered on top of its contingencies and caveats, Merck offers only a mere conclusory statement about a theoretical product as a purported allegation of patent infringement: "a ***corresponding version*** in the United States, on information and belief, . . . ***would*** contain mometasone furoate monohydrate and ***would*** infringe at least claim 1 of the '353 patent." (D.I. 24 ¶ 41). This is a truly speculative legal conclusion about a theoretical product, and certainly is not a factual allegation entitled to an assumption of truth. Using the language of *Iqbal*, Merck's statement is a "sweeping legal conclusion" based on "unwarranted inferences" that are "cast in the form of factual allegations." *See Phillips*, 2010 WL 3522787, at *4 (citing *Iqbal*, 556 U.S. at 678-79).

Accordingly, the complaint should be dismissed. *See, e.g.*, *Torrey*, 2014 WL 941308, at *18 (dismissing complaint for failure to state a claim because "the Court will not accept bald assertions, unsupported conclusions, unwarranted [in]ferences, or sweeping legal conclusions cast in the form of factual allegations" (citing *Iqbal*, 556 U.S. 678-79)).

* * *

CONCLUSION

For the reasons stated above, the amended complaint (D.I. 24) should be dismissed for failure to state a claim.[7]

Dated: June 29, 2015

Respectfully submitted,

APOTEX CORP.

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[7] The amended complaint names two defendants: Apotex Corp. and Apotex Inc. Merck has not yet served the amended complaint on Apotex Inc. Had Merck served Apotex Inc., it would not affect the merits of this motion, which apply to Apotex Inc. as well. The amended complaint is deficient and defective, and should be dismissed.